UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

May 8, 2019

OPP Decision Numbers: 547305; 548541; 548542
EPA File Symbols: 45728-GE; 45728-GG
Petition Number: 8F8740
Product Names: Chlormequat Chloride MUP; Adjust SL
EPA Receipt Date: 12/10/2018
EPA Company Number: 45728
Company Name: Taminco US LLC, A Subsidiary of Eastman Chemical Company

Jessica McLaughlin
Product Steward, North America
Taminco US LLC, A Subsidiary of Eastman Chemical Company
200 S. Wilcox Drive
Kingsport, TN 37600-5147

Dear Ms. McLaughlin:

The Agency has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide (FIFRA), as amended by the Pesticide Registration Improvement Extension Act. The Agency has determined that your application did not pass the preliminary technical screen and, therefore, must be rejected.

The Agency notified you of the failure on March 26, 2019 and your opportunity to correct your application within 10 business days of the receipt of that notice. In response, you submitted a rebuttal letter on March 27, 2019 responding to each of the deficiencies; on April 2, 2019 you submitted a waiver for guideline 835.4200 (anerobic soil metabolism study; and on April 9, 2019 you submitted an additional study for guideline 850.4500 (non-vascular aquatic plant toxicity study). Specifically, the following studies and/or waivers were either not submitted or do not fulfill the guidelines and are required for a proposed first food use.

The Agency's response to your submissions is as follows:

1. **Soil photolysis study (OCSPP 835.2410)** – You have cited accession number 137644 and MRID 41175802. 137644 is an unacceptable study and does not fulfill the data requirement. MRID 41175802 is an aqueous photolysis study, not a soil photolysis study. The data requirement at 40 CFR 158.1300 has not been satisfied.

2. **Anaerobic soil metabolism study (OCSPP 835.4200)** – You cited MRIDs 47769405; 47769406; and 47769407. These studies are not anaerobic soil metabolism studies. You subsequently submitted a waiver rationale which will be assigned a MRID. The Agency will not formally review the waiver until a complete application is submitted. However, should you decide to submit this proposed first food use application in the future, a meeting can be scheduled with the Agency to discuss this data waiver.

3. **The associated Independent Laboratory Validation (OCSPP 850.6100) for the Environmental Chemistry Method (ECM) in water** – A new study (MRID 50747517) was submitted to the Agency in response to the 10-day deficiency letter. The Agency acknowledges this submission but will not be reviewing this study until a complete application is submitted.

4. **Non-vascular aquatic plant toxicity study (850.4500)** – The Agency acknowledges that there are available data with the freshwater green algae *Desmodium subspicatus* (syn. *Scenedesmus subspicatus*) (MRID 46725222; acceptable). Additionally, you submitted MRID 50830001 on April 9, 2019 which was conducted with a different species of green algae; a taxa that the Agency already has available data on. However, in order to fulfill the 850.4500 guideline, testing with the marine diatom (*Skeletonema costatum*) and the freshwater diatom (*Navicula pelliculosa*) must also be conducted and submitted (EPA Ecological Effects Test Guidelines, OCSPP 850.4500: Algal Toxicity [rev. January 2012]). The data requirements at 40 CFR 158.630 has not been satisfied.[1]

5. **Chronic saltwater invertebrate (OCSPP 850.1350)** - This guideline data is required because the products with the proposed first food uses are expected to enter an estuarine/marine environment in significant concentrations causing potential for direct exposure. Therefore, regardless of the available acute toxicity endpoints, the Agency requires this data. The data requirement at 40 CFR 158.630 has not been satisfied.

6. **Chronic saltwater vertebrate (OCSPP 850.1400 or 850.1500)** - This guideline data is required because the products with the proposed first food uses are expected to enter an estuarine/marine environment in significant concentrations causing potential for direct exposure. Therefore, regardless of the available acute toxicity endpoints, the Agency requires this data. Guideline 850.1400 was listed in the Final Work Plan as a data need as well as in the Generic Data Call-In (GDCI) that is posted to the chlormequat chloride registration review docket (EPA-HQ-OPP-2015-0816). The data requirements at 40 CFR 158.630 have not been satisfied.

7. **Terrestrial plant toxicity studies (OCSPP 850.4100 and 850.4150)** – The two terrestrial plant toxicity studies submitted with your application were conducted with an end-use product (Manipulator™) rather than the product that is being proposed for

[1] The 850.5400 guideline was renumbered to 850.4500; see https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-850-ecological-effects-test-guidelines

registration (Adjust™ SL). In response to the 10-day deficiency letter you submitted additional evidence demonstrating that the formulated end-use products Adjust™ SL and Manipulator™ are the same formulation. The Agency has preliminarily screened this submission and believes this evidence sufficiently addresses our concerns. However, this submission will not be reviewed until a complete application is submitted.

Any future submissions to the Agency will be considered a new application and subject to the full registration service fee, as well as another initial content screen and preliminary technical screen.

You may be eligible for a partial refund as a result of your application's rejection for failure of its preliminary technical screening. Consult the Agency's Refund Policy at: http://www.epa.gov/pesticides/fees/fee-reduction-guidance.pdf. If you believe you are entitled to a refund, submit a refund request to the appropriate PRIA ombudsperson identifying the rejected application by decision number(s) and PRIA category.

If you have questions, please contact Heather A. Garvie at garvie.heather@epa.gov or 703-308-0034.

Sincerely,

RICHARD KEIGWIN

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Date: 2019.05.08 13:07:47 -04'00'

Richard P. Keigwin, Jr., Director
Office of Pesticide Programs
US Environmental Protection Agency